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| APPLICATION NO.  | FILING DA  | ATE        | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |
|--|------------|------------|----------------------|-------------------------|------------------|
| 10/089,300   | 05/15/2002 |            | Alfonso Valencia     | 108358-00015            | 7384             |
| 4372   | 7590 0     | 08/19/2004 |                      | EXAMINER                |                  |
|  | X KINTNER  |            | SMITH, CAROLYN L     |                         |                  |
| 1050 CONNECTICUT AVENUE, N.W. SUITE 400 WASHINGTON, DC 20036 |            |            |                      | ART UNIT                | PAPER NUMBER     |
|  |            |            |                      | 1631                    |                  |
|  |            |            |                      | DATE MAILED: 08/19/2004 |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

|   | Application No.   | Applicant(s)   |  |  |  |  |
|---|---|--|--|--|--|--|
| Office Action Summary   | 10/089,300  | VALENCIA ET AL.  |  |  |  |  |
| Office Action Summary   | Examiner  | Art Unit   |  |  |  |  |
|   | Carolyn L Smith   | 1631   |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply  |   |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply - If NO period for reply is specified above, the maximum statutory period v - Failure to reply within the set or extended period for reply will, by statute.  Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).        | 36(a). In no event, however, may a reply be tim<br>within the statutory minimum of thirty (30) days<br>will apply and will expire SIX (6) MONTHS from<br>cause the application to become ABANDONE                 | nely filed s will be considered timely. the mailing date of this communication. O (35 U.S.C. § 133). |  |  |  |  |
| Status  |   |  |  |  |  |  |
| 1)⊠ Responsive to communication(s) filed on <u>29 March 2002</u> .  |   |  |  |  |  |  |
|   | action is non-final.  |  |  |  |  |  |
|   | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. |  |  |  |  |  |
| Disposition of Claims   |   |  |  |  |  |  |
| <ul> <li>4)  Claim(s) 1-41 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) 1-41 are subject to restriction and/or election requirement.</li> </ul>  |   |  |  |  |  |  |
| Application Papers  |   |  |  |  |  |  |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) access Applicant may not request that any objection to the Replacement drawing sheet(s) including the correction of the oath or declaration is objected to by the Examine 11).  | epted or b) objected to by the Eddrawing(s) be held in abeyance. See ion is required if the drawing(s) is obj   | 37 CFR 1.85(a).<br>ected to. See 37 CFR 1.121(d).  |  |  |  |  |
| Priority under 35 U.S.C. § 119  |   |  |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul> |   |  |  |  |  |  |
| Attachment(s)   |   |  |  |  |  |  |
| <ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)         Paper No(s)/Mail Date     </li> </ol>  | 4) Interview Summary ( Paper No(s)/Mail Dai 5) Notice of Informal Pa 6) Other:  |  |  |  |  |  |

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## **Detailed Action**

Amended claims 4, 5, 6, 8, 9, 13, 14, 15, 17, 18, 20, 22, 23, 24, 25, 26, 27, 30, 32, 34, 35, 36, 38, 40, and 41, filed 3/29/02, are acknowledged.

## Restriction/Election

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-33, 36-37, and 40-41, drawn to a process, computer system, and computer readable medium for the determination for interacting molecules, classified in class 702, subclass 19 and class 211, subclass 41.12. If this Group is elected, then the below summarized specie election is also required.
- II. Claim 34, drawn to pairs of interacting bimolecules, classified in class 536, subclass 23.1 and class 530, subclass 350. If this Group is elected, then the below summarized specie election is also required.
- III. Claim 35, drawn to a data structure, classified in class 702, subclass 20. If this Group is elected, then the below summarized specie election is also required.
- IV. Claims 38-39, drawn to a database, classified in class 211, subclass 41.12. If this Group is elected, then the below summarized specie election is also required.

## **Specie Election Requirement for Groups I-IV:**

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This application contains claims directed to the following patentably distinct species of the claimed invention:

For All Groups:

Specie A: data that are DNA sequences

Specie B: data that are RNA sequences

Specie C: data that are amino acid sequences

Applicant is required under 35 U.S.C. 121 to elect a single disclosed specie for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. The distinctness or independence of DNA versus RNA versus amino acid sequences is because they are directed to different chemical types regarding the critical limitations therein. The completely separate chemical and entity types of the species are often separately characterized and published in literature, thus adding to the search burden if all species were examined together. Also, processing that may connect two species does not prevent them from being considered distinct because enough processing can result in the production of any composition from another composition as long as the processing is not limited in occurrences such as subtractions, additions, and enzymatic action. Thus, the three species are independent and/or distinct invention types for restriction purposes.

Applicant is advised that a reply to this requirement must include an identification of the specie that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should an applicant traverse the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because of the following reasons:

Inventions in Groups I-IV are related as product and the process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the pairs of interacting bimolecules of Group II may be utilized in distinct usages as needed in Group I determining of interacting bimolecules, in a data structure as in Group III, in a database as in Group IV, or alternatively, in a pharmaceutical composition. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

Action D. Warrely 8/18/04

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

August 16, 2004